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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/877,635	06/08/2001	James N. Herron	3278.2US	9774

24247 7590 07/29/2003

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EXAMINER
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LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 07/29/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/877,635

Applicant(s)

HERRON ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-33 is/are pending in the application.
- 4a) Of the above claim(s) 34-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 34-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 8.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 30 appears to have incorrect grammar in line 2, and thus it is unclear what Applicant is claiming.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-33 are rejected under 35 U.S.C. 103(a) as being unpatentable Foster, 5,485,277, in view of Jackowski, 5,747,274.

Foster discloses the invention substantially as claimed. Foster discloses an assay system comprising: a light source (50); a waveguide (60) having at least one planar surface; a first member (110) associated in liquid tight attachment with said at least one planar surface of said waveguide, wherein said first member, in conjunction with said waveguide, defines at least one reaction area for containing a sample while said at least one planar surface of said waveguide defines a floor or ceiling of said at least one reaction area, see column 8, lines 56-59 and Figure 4(b); a light detector (350) for detecting evanescent light passed through said planar surface and generating an intensity signal indicating an intensity of said detected light; and a controller (i.e., processor, see column 8, lines 60-63) for monitoring said intensity signal and being capable of correlating said intensity signal to a concentration of at least one indicator of coronary artery disease in the sample.

As to claim 22, said waveguide is optically associated with a rear lens (see column 7, line 66 – column 8, line 2) oriented for reading light from said light source passing through said waveguide, to monitor coupling efficiency and beam quality.

As to claim 24, said at least one reaction area comprises a reservoir, see column 8, lines 56-59.

As to claim 25, said at least one reaction area comprises a well, see column 8, lines 56-59, and Figure 4(b).

As to claim 26, said controller (i.e., processor) is capable of correlating in a substantially continuous fashion, see column 8, lines 60-63, and column 9 line 29 – column 10, line 40.

As to claims 27 and 29, said controller is capable of being configured to effect said monitoring and said correlating until a reliable determination is made of whether said at least one indicator of coronary artery disease is present in an amount indicative of coronary artery disease, see column 8, lines 60-63, and column 9 line 29 – column 10, line 40.

As to claims 28 and 30, said controller is capable of being configured to output a signal that effects reporting of said reliable determination, see column 8, lines 60-63, and column 9 line 29 – column 10, line 40.

As to claim 31, said controller is capable of being configured to substantially simultaneously determine concentrations of a plurality of indicators of coronary artery disease, see column 8, lines 60-63, and column 9 line 29 – column 10, line 40.

However, Foster does not specifically disclose that the planar surface has capture molecules for at least one indicator of coronary artery disease.

As to claim 23, Foster does not disclose that the capture molecules include capture molecules that bind with at least a portion of at least one of a troponin, creatine kinase, or myoglobin molecule or complex.

As to claim 32, Foster does not disclose that said capture molecules comprise capture molecules that bind with at least a portion of at least one ischemic marker or at least one complex that includes at least one ischemic marker.

As to claim 33, Foster does not disclose that said capture molecules comprise capture molecules that bind with at least a portion of at least one marker released from cardiac tissue only after a myocardial infarction or at least one complex that includes marker released from cardiac tissue only after a myocardial infarction.

Foster does teach that the system is used for biochemical studies using immobilized molecules for binding to molecules in samples, see column 8, lines 56-63, and see column 11, line 35 – column 12, line 58, and teaches use of a fluorescence detector, see column 16, lines 51-56.

Jackowski likewise teaches an assay system comprising immobilized molecules, a waveguide, see column 27, line 47 – column 28, line 11, and column 29, lines 1-31, and fluorescence detector, see column 28, lines 12-38. In addition, Jackowski teaches use of capture molecules that bind with troponin, creatine kinase, or myoglobin, see column 4, lines 35-36, and column 5, lines 29-31, for the detection of myocardial infarction, see column 4, lines 32- column 8, line 31, and column 19, lines 8-14, and column 29, lines 51-63, and column 29, lines 51-63, and column 22, lines 1-12, wherein the capture molecule is immobilized on a waveguide surface, see column 27, lines 38-58, and column 29, lines 1-27.

Jackowski further teaches that various techniques available in optical sensor technology are adaptable to the practice of the invention, see column 29, lines 28-31. Thus, it would have been obvious to utilize the waveguide and optical sensor system taught by Foster to have capture molecules for the detection of myocardial infarction, as

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taught by Jackowski, as a known waveguide and optical sensor system adaptable to the practice of the Jackowski invention.


### **Conclusion**


The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. DeMaeyet et al., 4,076,420, and Sutherland et al., 4,818,710, both disclose assay systems with waveguides and fluorescence detectors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

  
A.L.  
July 28, 2003

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

07/23/07